

No. 23-55742

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH, ET AL.,
Plaintiff-Appellee,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court for the Central
District of California, No. 2:17-cv-07223, Hon. John. W. Holcomb

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INTRODUCTION

Plaintiff’s response brief (“Resp.”) illustrates why no other court has certified a class like this one. Plaintiff concedes that over 40% of Actos prescriptions—millions of prescriptions written over more than a decade by countless doctors—were unaffected by the alleged disclosure failures. Plaintiff also concedes that at least *some* class members were completely uninjured and that it lacks any means of identifying these unharmed class members short of conducting full-blown individual trials. As a result, enormous numbers of individual inquiries would be necessary to resolve disputed issues of injury and causation and to separate uninjured TPPs from allegedly injured ones. Those individual inquiries should have defeated class certification, just as they have in many other similar class actions.

Plaintiff counters that it can bypass these individual inquiries by relying on Comanor’s estimates that 56% of prescriptions were “fraudulently induced” and that 98.5% of class members paid for a fraudulently-induced prescription. Resp. 60-61. But Plaintiff effectively admits that the district court never conducted the “rigorous analysis” of Comanor’s estimates required by Rule 23. Instead, as Plaintiff recognizes, the court simply took those estimates “at face value” after finding them admissible under *Daubert*. See Resp. 46-47. That error alone requires reversal, because controlling precedent in this Circuit holds that a mere *Daubert* admissibility analysis is no substitute for the rigorous analysis required by Rule 23. See, e.g., *Ellis*

v. Costco Wholesale Corp., 657 F.3d 970, 982-84 (9th Cir. 2011). When Comanor's estimates are assessed under a rigorous Rule 23 standard, they plainly fail to satisfy Rule 23(b)(3)'s predominance requirement: they rest on admittedly false assumptions, and they cannot even be *applied* to individual TPPs without a host of predominance-destroying individual inquiries into the essential factual premises of Comanor's estimates.

Even if Comanor's flawed and inaccurate estimates could survive a rigorous Rule 23 analysis (and they cannot), they still would fail to prove predominance. Those estimates will not preclude Defendants from raising vast numbers of doctor-by-doctor challenges to Comanor's probabilistic assertion that 98.5% of class members likely were injured. Nor will those estimates avoid the thousands of individual mini-trials that would be necessary to separate the 98.5% of class members that Comanor claims were probably injured from the other 1.5%. Even Plaintiff appears to recognize that these individual inquiries would turn a class-action trial into "nightmare," *see* Resp. 72, particularly when Lilly's unique circumstances are taken into account. The class certification order should be reversed.

ARGUMENT

I. The District Court Erred By Taking Comanor’s Estimates “At Face Value.”

A. The district court’s failure to conduct a rigorous analysis of Comanor’s estimates requires reversal.

Plaintiff all but admits that the district court applied the wrong legal standard in finding that Plaintiff satisfied the predominance requirement. The court found that Plaintiff met that requirement because, “[t]aking Comanor’s analysis at face value,” it shows that 56% of Actos prescriptions were fraudulently induced and 98.5% of class members paid for a fraudulently-induced prescription. 1-ER-22. But the court never conducted a “rigorous analysis” of those estimates as required by Rule 23. Instead, it simply took those estimates “at face value,” declined to “weigh Comanor’s testimony” or assess its “accuracy,” and refused to consider any “contradicting evidence or testimony from Takeda’s experts.” 1-ER-22 & n.88.

Plaintiff defends that deferential approach to Comanor’s estimates by asserting that the district court “did exactly what was required of it” when it analyzed Comanor’s estimates under a *Daubert* standard and held that they “pass[] muster under *Daubert*.” Resp. 46. As shown below, Plaintiff’s reliance on a *Daubert* analysis is a confession of error: this Court’s precedent holds that district courts commit reversible error where, as here, they substitute a *Daubert* admissibility analysis for the rigorous analysis required by Rule 23.

1. The district court’s *Daubert* approach conflicts with controlling precedent.

Nowhere in Plaintiff’s 74-page brief does it purport to identify any “rigorous analysis” of Comanor’s estimates in the order granting class certification. Instead, Plaintiff points to the district court’s separate *Daubert* order and argues that the court engaged in the requisite “rigorous analysis” when it “conducted a *Daubert* analysis” and found that Comanor’s report “passes muster under *Daubert*.” Resp. 46-47.

Controlling precedent rejects that argument. In *Ellis*, this Court vacated a class certification order where the district court “confuse[d] the *Daubert* standard ... with the rigorous analysis standard” and “end[ed] its analysis of the plaintiffs’ evidence after determining such evidence was merely admissible.” 657 F.3d at 982.¹ In *Grodzitsky v. Am. Honda Motor Co.*, 957 F.3d 979, 986 (9th Cir. 2020), this Court reiterated that a district court “must engage in a rigorous analysis” of expert evidence offered to satisfy Rule 23 requirements rather than “limit[ing] its analysis ... to a determination of whether Plaintiffs’ evidence ... was admissible.” And in *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 666 & n.9 (9th Cir. 2022), this Court emphasized that “[c]ourts have frequently found that expert evidence, while otherwise admissible under *Daubert*, was inadequate to satisfy the prerequisites of Rule 23.”

¹ Unless otherwise specified, internal quotation marks, emphases, alterations, and citations are omitted, and emphasis is added.

The class certification order flouts this precedent. Defendants made an extensive showing that, even if admissible, Comanor’s estimates fail to prove predominance because they rest on “unsupported assumptions” and cannot prove injury and causation “for the entire class.” *See Olean*, 31 F.4th at 666 n.9. If that showing has merit, then class certification was improper because Plaintiff cannot “appropriately use generalized proof” to prove injury and causation, and individualized inquiries into injury and causation will predominate over common questions. *See UFCW Loc. 1776 v. Eli Lilly & Co. (“Zyprexa”)*, 620 F.3d 121, 131-32 (2d Cir. 2010). The district court was thus required to “judg[e] the persuasiveness of the evidence presented,” *Ellis*, 657 F.3d at 982, “weigh[] conflicting expert testimony,” *Olean*, 31 F.4th at 666, and determine whether Plaintiff “prove[d] the facts necessary to carry the burden of establishing [predominance] by a preponderance of the evidence,” *id.* at 665. But none of that happened. The court’s wholesale failure to conduct this analysis is reversible error. *See Ellis*, 657 F.3d at 982 (error to conduct only a *Daubert* analysis of plaintiffs’ expert evidence); *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 192-93 (3d Cir. 2020) (error to accept “expert testimony ... without conducting a rigorous analysis of the competing expert reports and resolving the competing factual disputes on which the reports rely”); *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008) (error to “uncritically accept[]” expert testimony “as establishing a Rule 23

requirement merely because the court [determined] the testimony should not be excluded[] under *Daubert*"); 1 *McLaughlin on Class Actions* § 3:14 (20th ed. 2023) ("It is reversible error to certify a class simply on the basis that proffered expert analysis is admissible.").

The district court should have resolved the disputes about Comanor's estimates "before class certification" because those disputes "bear on Rule 23's predominance requirement." *Goldman Sachs Grp., Inc. v. Ark. Tchr. Ret. Sys.*, 594 U.S. 113, 119 (2021). Indeed, Comanor's 56% and 98.5% estimates were the linchpin of the district court's predominance analysis. Only by assuming the truth of those estimates was the court able to find that "common evidence of injury would ... be expected to apply to ... 98.5% of the class," 1-ER-22; that Plaintiff had "statistically limit[ed] the number of uninjured TPPs to a *de minimis* level," 1-ER-32; and that "common questions are more likely to predominate," *id.*² Accordingly, if Defendants are correct that Comanor's estimates rest on false and unfounded assumptions, the "essential precondition" of the court's predominance analysis

² Although Plaintiff cites "internal email conversations" and "academic studies" in addition to Comanor's estimates (Resp. 42), this alternative evidence is insufficient because it does not purport to show which TPPs (if any) were injured. The district court made no finding that Plaintiff could prove predominance without Comanor's estimates; nor could it have. See *In re Rail Freight Fuel Surcharge Antitrust Litig. ("Rail Freight II")*, 934 F.3d 619, 623 (D.C. Cir. 2019) (predominance not proven by "documentary evidence" and "inconclusive" studies that failed to account for "causes besides any conspiracy").

“completely collapses, rendering class certification inappropriate.” *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 282, 283 (2014). That is why the district court should have conducted a “rigorous analysis” of Comanor’s estimates and resolved the key disputes about those estimates *before* certifying a class. *See, e.g., Goldman Sachs*, 594 U.S. at 119 (viability of proposed common proof must be proven “before class certification”); *Halliburton*, 573 U.S. at 283 (same); *Comcast Corp. v. Behrend*, 569 U.S. 27, 34-35 (2013) (requiring “rigorous analysis” of expert model at certification stage).

The district court’s contrary approach of deferring to Comanor’s estimates based simply on their admissibility sets the bar for class certification far too low. Under that approach, *any* admissible expert evidence that merely *purports* to prove classwide injury and causation would be sufficient to prove predominance, no matter how flawed or inaccurate it might be. “Such a proposition would reduce Rule 23(b)(3)’s predominance requirement to a nullity.” *Comcast*, 569 U.S. at 35-36. Put differently, the district court’s lax approach to class certification “amounts to a delegation of judicial power to the plaintiffs, who can obtain class certification just by hiring a competent expert.” *West v. Prudential Sec., Inc.*, 282 F.3d 935, 938 (7th Cir. 2002). And that is exactly what happened here.

As this Court recognized in *Ellis*, *Grodzitsky*, and *Olean*, it is no answer to say that *Daubert* provides a sufficient check on expert evidence at the class-

certification stage. *Daubert* is not as demanding as Rule 23’s “stringent requirements,” which “in practice exclude most claims.” *Am. Exp. Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013). Furthermore, “a determination that proffered expert testimony is reliable [under *Daubert*] does not indicate, in any way, the correctness or truthfulness of such an opinion,” *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529, 530 (3rd Cir. 2008); nor does such a determination indicate that the expert is answering the right question. For these reasons, courts often deny or reverse class certification even where the plaintiffs offer admissible expert evidence that purports to prove classwide injury.³ The district court’s lax approach to class certification would reverse the results in all those cases and open the doors to class certification to any expert resourceful enough to survive *Daubert*.

2. *Tyson* does not support the district court’s approach.

Unable to reconcile the district court’s decision with this Court’s precedent, Plaintiff falls back on the Supreme Court’s statement that, “[o]nce a district court finds evidence to be admissible, its persuasiveness is, in general, a matter for the jury.” Resp. 45 (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 459 (2016)). But as *Olean* recognized, that language in *Tyson* refers to evidence offered to prove “the merits of a common question,” not to evidence offered to prove Rule

³ See, e.g., *Comcast*, 569 U.S. at 33 n.4; *Lamictal*, 957 F.3d at 192-93; *Rail Freight II*, 934 F.3d at 623; *Ellis*, 657 F.3d at 982-84; *Zyprexa*, 620 F.3d at 129, 135; *Hydrogen Peroxide*, 552 F.3d at 315 & n.13, 323-24.

23 requirements. *See Olean*, 31 F.4th at 667. Here, the disputes over Comanor’s estimates go directly to the Rule 23 question whether injury and causation are common questions or individual ones, *i.e.*, whether injury and causation are “susceptible to generalized proof” or whether individual evidence will be necessary to resolve those questions. *See Zyprexa*, 620 F.3d at 131-33, 136. If Defendants’ challenges to Comanor’s estimates are correct, then injury and causation are individual questions—not common ones—because Plaintiff cannot “appropriately use generalized proof” to resolve them on a classwide basis. *Id.* at 131-32. Under settled law, Rule 23 questions like these must be resolved before class certification “even when that requires inquiry into the merits.” *Goldman Sachs*, 594 U.S. at 119, 122.

The facts in *Tyson* illustrate the point. There, a class of employees sued their employer for overtime pay, but the employees faced an “evidentiary gap created by the employer’s failure to keep adequate records” that “forced [them] to rely on ... representative evidence” to prove their claims. 577 U.S. at 450, 456-57. The employer’s recordkeeping failures also generated a statutory presumption that “representative evidence” was sufficient to prove the claims of individual employees “as a matter of just and reasonable inference.” *Id.* at 456. The employer nevertheless sought a “broad” and “categorical” rule that representative evidence could not be used to prove the employees’ claims, *id.* at 454, 459, but “[t]hat defense [was] itself

common to the claims by all class members,” *id.* at 457. “Since there were no alternative means for the employees to establish their hours worked,” a finding in the employer’s favor on that question would have created a “fatal similarity” within the class: it “would have ended the litigation and thus would not have caused individual questions to overwhelm questions common to the class.” *Id.* *Tyson* thus held that the sufficiency of the employees’ representative evidence presented a *pure merits question* that had no bearing on Rule 23 requirements. *Id.*

This case presents no analog. Unlike *Tyson*, this is not a case in which an “evidentiary gap” leaves TPPs with “no alternative means” of proving injury and causation other than Comanor’s estimates; nor is it a case in which a finding that Comanor’s estimates are defective would create a “fatal similarity” within the class. *See Tyson*, 577 U.S. at 456-57. Instead, individualized evidence exists here in abundance, *see* Defs. Opening Br. (“Br.”) 42-45, and a finding that Comanor’s estimates are defective would still “leave[] open the prospect of individualized proof,” *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 473-74 (2013). Accordingly, a failure of Comanor’s purported “common proof” would expose a fatal *dis*-similarity among class members: class members would lack any *common* evidence capable of proving injury and causation on a classwide basis, and the case would revert to the “traditional mode” of assessing those elements through “individualized proof.” *Id.* at 473-74. Because individualized inquiries into injury

and causation inevitably would predominate in any such litigation, the litigation “could not be certified under Rule 23(b)(3) as a class action.” *Id.*

Finally, even under Plaintiff’s overbroad reading of *Tyson*, *Tyson* would apply here only if “*each* class member could have relied on [Comanor’s estimates] to establish liability.” Resp. 37 (quoting *Tyson*, 577 U.S. at 455). But Comanor does not purport to establish liability for “each” class member or even for any *individual* class member: he estimates that 98.5% of class members were injured—not 100%—and he has no means of identifying which class members are among his 98.5% and which are among his 1.5%. *See* Br. 51-54. For this reason as well, *Tyson* does not apply here.

B. Comanor’s estimates cannot withstand rigorous analysis.

Although Defendants made a compelling showing in the district court that Comanor’s estimates fail to prove predominance because they “contain[] unsupported assumptions” and are “inadequate to prove [injury and causation] for the entire class,” *see Olean*, 31 F.4th at 666 n.9, the district court never evaluated that showing under a rigorous Rule 23 standard. This Court has discretion either to apply that standard itself or to remand to the district court to do so. *See Lozano v. AT&T Wireless Servs., Inc.*, 504 F.3d 718, 730-31 (9th Cir. 2007). The Court should apply the correct standard itself and reverse class certification because “it is clear

that, under the proper standard for evaluating certification,” Comanor’s evidence “falls far short of establishing” predominance. *Comcast*, 569 U.S. at 34.

1. Comanor’s simplistic market-share extrapolation cannot withstand rigorous analysis.

Plaintiff does not deny—nor could it—that Comanor arrived at his 56% estimate by assuming that but-for the alleged disclosure failures, Actos would have had the same average market share from 1999 through 2011 that it had in December 2013. Comanor assumed, in other words, that the alleged disclosure failures are *the only reason* Actos prescriptions were 56% lower in December 2013 than they were from 1999 through 2011. Even Comanor concedes that this assumption is wrong, and uncontroverted evidence reinforces that concession. Br. 30-32. Comanor’s estimates thus rest on “unsupported assumptions” that render them “inadequate to satisfy the prerequisites of Rule 23.” *Olean*, 31 F.4th at 666 n.9; *see also Zyprexa*, 620 F.3d at 135 (rejecting expert’s unsupported assumption that “every prescription above the number of prescriptions written [after safety disclosures] was an ‘excess’ prescription”); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 90-92 (2d Cir. 2015) (rejecting expert estimate that “simply assumed that a downturn in [prescriptions] was attributable to the disclosure of ... safety risks”).

Plaintiff responds with the misleading assertion that Comanor “accounted for numerous market factors” in his regression models. Resp. 48. But all Plaintiff is

saying is that Comanor accounted for various market factors at the *first* step of his analysis that examined the *actual* world, not that he did so in the all-important *second* step that sought to show how the *but-for* world allegedly would have differed from the actual world. At the first step of his analysis, Comanor used regression models to analyze the actual world and concluded that the alleged nondisclosures had an unquantified effect on the number of Actos prescriptions. Br. 29. At the second step, he used a crude market-share extrapolation to estimate the but-for world and concluded that 56% of Actos prescriptions were fraudulently induced. *Id.* While Comanor attempted to account for other factors in his models of the *actual* world, he did nothing at all to account for other factors in his estimate of the *but-for* world. Instead, he estimated the but-for world by simply using Actos’s December 2013 market share as a “benchmark” and extrapolating backwards to 1999, without making *any* effort to account for market changes between 1999 and 2013. 3-ER-386-87, 407-10. That is all Plaintiff means when it states: “Then, [Comanor] used that [December 2013] benchmark to estimate how many prescriptions ... would have occurred regardless of the fraud.” Resp. 49.

Plaintiff engages in further obfuscation when it asserts that “Comanor *did* use regression” to “predict Actos market share at the end of December 2013.” Resp. 48. As an initial matter, Actos’s December 2013 market share is readily available, so Comanor’s decision to “predict” that market share rather than simply looking it up

is “superfluous.” 3-ER-386-87. But even setting that superfluous decision aside, Comanor’s market-share extrapolation is defective *regardless* of whether he starts from a predicted figure or an actual figure for Actos’s December 2013 market share. Either way, a crude backward extrapolation from December 2013 is unsound because it falsely assumes that there were *no* relevant market changes from 1999 to 2013. *Id.*

To illustrate the point, suppose a researcher used a regression model to “predict” today’s temperature instead of looking up today’s actual temperature. If the researcher labeled that prediction a “benchmark” and used it to estimate that exactly the same temperature should have existed for the prior twelve months, it would be grossly misleading to say that those estimates are the product of a regression model or that they account for all atmospheric changes over the last twelve months. Comanor’s analysis takes exactly this form. He used a regression model to predict an actual-world value he could have simply looked up—Actos’s December 2013 market share—and then arbitrarily assumed that the same market share should have existed for the 12-year period from 1999 through 2011. Uncontroverted evidence refutes that false assumption. *See* Br. 31-32; 3-ER-264-66, 374-75, 382-88, 408-11.

Comanor’s 56% estimate is thus “akin to the simplistic proof introduced by the *Zyprexa* plaintiffs, and not to the far more sophisticated proof offered in

Neurontin.” *Sergeants*, 806 F.3d at 97. That estimate is simply “an extrapolation from the fact that the number of ... prescriptions ... fell after [the alleged] fraud became known.” *Id.* at 96 (quoting *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 46 (1st Cir. 2013)). In the *Neurontin* cases, by contrast, the plaintiffs’ expert did exactly what Comanor failed to do here: she used a regression model that accounted for other market factors to estimate the number of prescriptions that would have been written in the but-for world.⁴ Comanor’s contrary approach of accounting for other market factors only in his estimates of the actual world, and not in his predictions of the but-for world, provides no viable “generalized proof” of injury and causation. *See, e.g.*, Br. 29-34; *Sergeants*, 806 F.3d at 96-97; *Zyprexa*, 620 F.3d at 135-36; *City of Rockford v. Mallinckrodt ARD, Inc.*, 2024 WL 1363544, at *8 (N.D. Ill. 2024) (denying certification where Comanor’s “yardstick” model “ma[de] no effort to control for any other factors” affecting a medication’s price); *see also Mier v. CVS Health*, 2023 WL 4837851, *1 (9th Cir. 2023) (rejecting certification where model failed to account for market factors).

⁴ In each *Neurontin* case cited by Plaintiff, the plaintiff’s expert offered her model only to prove injury to a single TPP—not a class of *thousands* of TPPs—and she used a well-controlled regression model to estimate the but-for world. *See* Br. 34; *Sergeants*, 806 F.3d at 96-97 (distinguishing *Neurontin*); *In re Neurontin*, 712 F.3d at 30, 46 (expert accounted for other factors and did not simply “extrapolat[e]” from the number of prescriptions written “after [the alleged] fraud became known”); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 51, 56 (1st Cir. 2013) (same model); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 60, 68 & n.10 (1st Cir. 2013) (same model).

Plaintiff also asserts that this Court “disagreed with *Zyprexa*” (Resp. 53) when it held that Plaintiff adequately alleged “proximate causation” at the pleading stage by alleging that “prescribing physicians ... relied on Defendants’ [alleged] misrepresentations.” *Painters & Allied Trades v. Takeda Pharm.*, 943 F.3d 1243, 1260 (2019). Plaintiff’s assertion again is misleading: the issue here is not whether Plaintiff alleged *proximate* causation at the pleading stage, but whether Plaintiff proved at the class-certification stage that *but-for* causation and injury are susceptible to generalized proof. *See id.* at 1248 & n.6 (expressing no opinion on but-for causation and injury). Comanor’s 56% estimate cannot prove those propositions because it rests on false assumptions and cannot identify which “prescribing physicians ... relied on Defendants’ [alleged] misrepresentations.” *Id.*⁵

Finally, Plaintiff cites *Olean* for the proposition that Comanor’s crude market-share extrapolation is “an accepted method of estimating” injury and causation. Resp. 50. *Olean*, however, says no such thing. The plaintiffs’ expert in *Olean* did exactly what Comanor failed to do here: he used regression models to estimate the but-for world, accounted for other factors that could have “affect[ed] the price” of the relevant product, and “isolate[d] the effect that the conspiracy *by itself* had on

⁵ Although Plaintiff incorrectly suggests that *Zyprexa* and *Sergeants* rejected simplistic extrapolations like Comanor’s in *dicta* (Resp. 53-54), those discussions are holdings or alternative holdings that “cannot be dismissed as *dicta*.” *Ass’n des Éleveurs de Canards et d’Oies du Québec v. Bonta*, 33 F.4th 1107, 1117 (9th Cir. 2022).

the prices paid by [plaintiffs].” *Olean*, 31 F.4th at 671-72. Furthermore, the district court in *Olean* did exactly what the district court here declined to do: it conducted a rigorous Rule 23 analysis of both sides’ expert evidence, “review[ed] each of the experts’ analyses,” and “resolv[ed] each dispute between the experts” before accepting the plaintiffs’ evidence as viable generalized proof of classwide injury. *Id.* at 675-76. None of that happened here. *Olean* thus lends no support either to Comanor’s crude market-share extrapolation or to the district court’s improper acceptance of that extrapolation “at face value.” 1-ER-22.⁶

2. Comanor’s “independent prescriptions” assumption cannot withstand rigorous analysis.

Comanor’s estimate that 98.5% of class members were injured relies on an additional unproven assumption that independently defeats class certification: it assumes each class member paid for five statistically “independent” Actos prescriptions. Since Plaintiff has no way of proving that indispensable assumption without conducting tens of thousands of individual inquiries into individual prescriptions and the doctors who wrote them, individual inquiries into “independence” will predominate over common questions in this litigation.

⁶ Plaintiffs’ other citations on this point are equally inapposite. *See In re Urethane Antitrust Litig.*, 768 F.3d 1245, 1256-57 (10th Cir. 2014) (defendants waived any challenges to plaintiffs’ regression model, and plaintiffs “did not seek to prove ... liability through extrapolation”); *In re Linerboard Antitrust Litig.*, 305 F.3d 145 (3rd Cir. 2002) (plaintiffs relied on multiple forms of proof including “multiple regression analysis” to estimate but-for prices).

Plaintiff concedes—as it must—that Comanor’s 98.5% estimate rests on an underlying assumption that each TPP paid for at least five “independent” prescriptions. Resp. 31. To prove that assumption and avail itself of Comanor’s 98.5% estimate, Plaintiff must show that each such prescription was truly “independent,” *i.e.*, that it had no statistical relationship to any other prescription. Comanor admitted as much in his expert report, explaining that “probability theory ... requires us to make [the] explicit assumption[] ... that claims are independent of each other such that the presence of a claim based on fraudulent information *does not alter the probability* of the same outcome in another claim.” 4-ER-539-40. Comanor had no choice but to make that exacting assumption because prescriptions are statistically “independent” of each other only “when the probability of one is unaffected by the occurrence or non-occurrence of the other.” National Research Council, *Reference Manual on Scientific Evidence* 288 (3d. ed. 2011).

Nowhere in Plaintiff’s brief does it attempt to show that it can prove each class member paid for five “independent” prescriptions without engaging in enormous numbers of predominance-destroying individual inquiries. Instead, Plaintiff runs away from what “independent” means: it redefines “independent” to mean something far less than true statistical independence, in direct contradiction of the “explicit assumption” employed in Comanor’s report. 4-ER-539-40. According to Plaintiff’s redefinition, “[a]n independent prescription is merely a *new* prescription,

i.e., not a refill.” Resp. 31; *see also id.* at 62 (“An independent prescription is simply ... a non-refill.”). But Plaintiff’s *ipse dixit* assertion that all prescriptions other than refill prescriptions are statistically independent of each other does not make it so. Plaintiff bore the burden of *proving* this essential premise of Comanor’s 98.5% estimate “by a preponderance of the evidence,” *Olean*, 31 F.4th at 665, and it never did so.

Far from providing any proof that all non-refill prescriptions are independent of each other, Comanor admitted that he *does not know* which prescriptions were truly “independent of each other” versus which were linked to each other because they were written or paid for by the same doctors, medical practices, or TPPs. *See* 4-ER-539-40. For example, according to Comanor, to know whether “prescriptions written by the same physician [are] independent,” “[y]ou would need to know a lot more about prescribing habits and how physicians treat different patients.” 3-ER-319-20. Comanor “would need to study” those questions, “and I have not done so.” *Id.*

Uncontroverted evidence reinforces Comanor’s admissions. As Professor Hughes explained, “many prescriptions that are not refills” are not “independent” of each other because “[a] physician who gains experience using Actos for one patient may apply that experience and increase the likelihood that the physician will prescribe Actos to a second patient.” 3-ER-368-69. In addition, evidence cited by

Plaintiff indicates that different prescribers had vastly different reactions to warnings about bladder cancer, with some reducing their prescriptions “to almost nil,” while the “prescription behavior [of nearly half of prescribers] has not overtly changed.” 4-SER-568; *see also* 2-ER-63. Moreover, even prescriptions written by different prescribers may be causally connected to each other if, for example, both prescribers were part of the same medical practice or relied on the same medical literature. 3-ER-369.

In sum, Comanor’s crucial assumption that all non-refill prescriptions are “independent” of each other is yet another “unsupported assumption” that fails to withstand rigorous analysis and renders his 98.5% estimate “inadequate to satisfy the prerequisites of Rule 23.” *Olean*, 31 F.4th at 666 n.9. The district court bypassed this fatal problem when it accepted Comanor’s estimate “at face value” and disregarded uncontroverted evidence showing that individual inquiries are necessary to establish true “independence.”

3. Comanor’s “alternative treatment” assumption cannot withstand rigorous analysis.

Comanor’s 98.5% estimate also rests on an admittedly false assumption that *all* alternative treatments that TPPs would have paid for in the but-for world would have been cheaper than Actos. *See* Br. 39-40. In its brief, Plaintiff does not even pretend this assumption is true. Nor does it deny that individual inquiries will predominate if RICO injury requires consideration of alternative treatments.

Instead, Plaintiff seeks to dismiss this problem by characterizing it as a “damages” issue rather than an “injury” issue. Resp. 64. Plaintiff is wrong: “showing injury” in a RICO action like this one requires an analysis of “what the alternatives to an ‘excess’ prescription would have been,” and whether those “possible alternatives ... would have been less expensive.” *Zyprexa*, 620 F.3d at 135-36.⁷ Individual inquiries into this *injury* issue defeat predominance.

Plaintiff responds with a radical argument that even a TPP that *saved* money by paying for Actos rather than “more expensive alternative[s]” suffered RICO injury. Resp. 65. But RICO injury is limited to “concrete financial loss,” *Chaset v. Fleer/Skybox Int’l, LP*, 300 F.3d 1083, 1086-87 (9th Cir. 2002), and TPPs had no concrete financial loss if they would have paid more for alternative treatments in the but-for world. That is especially obvious in this case, in which no one denies that Actos was medically effective and Plaintiff seeks no recovery for any alleged health consequences of taking Actos. Particularly in those circumstances, “excess prescriptions may not have actually caused loss, given the likelihood of substitute prescriptions.” *Zyprexa*, 620 F.3d at 135-36.⁸

⁷ This Court’s observation in *Painters I* that less expensive alternatives may present a “damages question” is not to the contrary. 943 F.3d at 1252 n.7. Injury was “not dispute[d]” in that appeal, *id.* at 1248, and this Court observed that Plaintiff would need to show that “the alternative drugs they would have paid for cost less than Actos” to be entitled to any recovery at all. *Id.* at 1252 n.7.

⁸ Since alternative treatments raise an injury issue in addition to a damages issue, Plaintiff’s vague suggestion that it can calculate damages by deducting a crude proxy

Plaintiff fails to cite a single RICO case to support its contrary argument that alternative treatment costs should be disregarded. Instead, it cites *Federal Trade Commission v. Figgie International, Inc.*, 994 F.2d 595 (9th Cir. 1993), a case involving the equitable remedy of disgorgement under the FTC Act. *See* Resp. 66. No such “equitable action should be implied under civil RICO,” *Religious Tech. Ctr. v. Wollersheim*, 796 F.2d 1076, 1088 (9th Cir. 1986), which has a “comprehensive and reticulated scheme” that “rul[es] out disgorgement,” *U.S. v. Philip Morris USA, Inc.*, 396 F.3d 1190, 1200-01 (D.C. Cir. 2005); *see also Laparade v. Ivanova*, 116 F. App’x 100, 104 (9th Cir. 2004) (“Disgorgement is an equitable remedy.”). Plaintiff thus lacks any cogent defense of the false alternative treatment assumption at the heart of Comanor’s 98.5% estimate.

II. The District Court Erred By Disregarding Defendants’ Individualized Challenges To Injury And Causation.

Even if Comanor’s estimates could survive a rigorous Rule 23 analysis, Defendants’ individualized challenges to injury and causation still would predominate over common questions at trial. The district court acknowledged that these individualized challenges are substantial: Defendants are entitled to present testimony from individual physicians “that they would have continued to prescribe Actos” in the but-for world; “a trier of fact could ... rely on the physicians’ testimony

for “the value received from the Actos purchased”—whatever that means—is irrelevant. *See* Resp. 70.

to qualify, discredit, or reject Plaintiffs’ common evidence of but-for causation”; and “a real and significant risk exists that individualized factual determinations would swamp common ones.” 1-ER-29. As a result, “[i]t remains an open question” whether Plaintiff can “successfully leverage common evidence ... without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones.” *Id.* That conclusion should have been dispositive: if it remains an “open question” whether individual issues will overwhelm common ones, then by definition Plaintiff failed to “prove the facts necessary to carry the burden of establishing [predominance] by a preponderance of the evidence.” *Olean*, 31 F.4th at 665.

The district court nevertheless certified a class, and Plaintiff now defends that erroneous decision on two grounds. Neither has merit.

First, Plaintiff attempts to shift the burden to Defendants to prove that Defendants’ so-called “affirmative defense to but-for causation” would predominate at trial. Resp. 56-57, 59. Defendants, however, bear no such burden. Plaintiff proceeds from the mistaken premise that lack of injury and causation are “affirmative defenses” on which “the defendant bears the burden.” Resp. 56. In reality, injury and causation are elements of Plaintiff’s RICO claim that Plaintiff must prove for each class member. *See* Br. 20-21. Plaintiff’s citation to *True Health*

Chiropractic, Inc. v. McKesson Corporation, 896 F.3d 923, 931 (9th Cir. 2018)—a case that involved a true affirmative defense (consent)—is thus inapposite.

In any event, regardless of whether an individualized issue arises from an element of a plaintiff’s claim or an affirmative defense, “the plaintiff bears the burden of proving that class issues predominate over individualized issues.” *Van v. LRR, Inc.*, 61 F.4th 1053, 1067 n.11 (9th Cir. 2023). Moreover, “the entire point of a burden of proof is that, if doubts remain about whether the standard is satisfied, the party with the burden of proof loses.” *Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1233-34 (11th Cir. 2016). As a result, “[a] district court that has doubts about whether the requirements of Rule 23 have been met should refuse certification until they have been met.” *Id.* Here, the district court violated that requirement by certifying a class despite an “open question” as to whether individualized issues will predominate. 1-ER-28-29.

Second, having improperly flipped the burden to Defendants to disprove predominance, Plaintiff argues that Defendants did not meet that burden because they failed to show that “individualized issues bar recovery on at least some claims.” Resp. 58. That argument is baffling: Plaintiff has *admitted* that individualized issues bar recovery on at least some claims. Comanor purports to show only that 98.5% of class members were injured—not 100%. Similarly, Plaintiff argues that “the likelihood of a class member being uninjured is ... 1.5%”—not zero—and concedes

that at least a “de minimis” number of class members were unharmed. Resp. 61, 62; Dkt. 258 at 9. Since individualized issues will “bar recovery on at least some claims,” Defendants have “summon[ed] the spectre of class-member-by-class-member adjudication.” *Van*, 61 F.4th at 1067, 1069. Plaintiff—not Defendants—therefore bore the burden of proving that these “class-member-by-class-member assessment[s]” will be either “unnecessary or workable,” *id.* at 1069, and it never made that showing.

Plaintiff insists that these individualized issues are “theoretical” and “speculative” because Defendants offered only “two depositions of prescribers” to substantiate them.⁹ Resp. 55, 57. But Plaintiff has *conceded* the point that those depositions were offered to establish: millions of Actos prescriptions still would have been written in the but-for world. For precisely that reason, the district court recognized that “a real and significant risk exists that individualized factual determinations would swamp common ones on the question of but-for causation.” 1-ER-29. That risk is magnified by the large number of small TPPs that paid for only a handful of prescriptions. *See* Br. 42. Particularly under those circumstances,

⁹ Although Plaintiff asserts without citation that the prescriptions written by these two prescribers “were not even part of the RICO class,” Resp. 57, that is wrong. Both prescribers worked at facilities operated by a class member, and the prescriptions at issue were covered by a class-member health plan. 2-ER-63, 68-69.

it does not matter whether Defendants provided “two or eighteen examples” to “substantiate[] the individualized issue.” *Van*, 61 F.4th at 1068 n. 13.

Taken together, Defendants’ examples and Plaintiff’s admissions raised the prospect of individualized challenges beyond the speculative level. Plaintiff’s contrary argument repeats the same error made by the district court: it focuses on a simplistic “tally” of the evidence deposited into the class-certification record, 1-ER-31, instead of “formulat[ing] some prediction as to how specific issues will play out” at trial, *Lamictal*, 957 F.3d at 190.

III. The District Court Erred By Ignoring The Individual Inquiries Necessary To Identify Uninjured Class Members.

Even if Comanor’s error-ridden 98.5% estimate could be taken at face value, it would not prove predominance. Plaintiff concedes that at least *some* of the tens of thousands of class members were uninjured. These TPPs “cannot prevail on the merits, so their claims must be winnowed away as part of the liability determination.” *Rail Freight II*, 934 F.3d at 624. And Plaintiff has no way to “segregate the uninjured from the truly injured” short of combing through the entire class in “full-blown individual trials” that defeat predominance. *Id.* at 625.

Plaintiff’s two responses are unavailing. *First*, Plaintiff asserts that the presence of a “de minimis” number of unharmed class members does not necessarily defeat predominance. Resp. 60-61. But Article III, RICO, and the Rules Enabling Act prohibit even a *single* uninjured TPP from prevailing on liability or obtaining a

recovery. *See* Br. 49-50; Resp. 60 (“Before a TPP can recover under RICO, it must be injured.”). Accordingly, the relevant question is not how many class members ultimately were unharmed, but how many individual inquiries will be necessary to “winnow away” those unharmed class members. *Rail Freight II*, 934 F.3d at 624. In other words, “[t]he question is not whether a great number of plaintiffs will win or lose” on the issue of injury, but whether the individual inquiries necessary to identify uninjured class members are “limited to a small number of class members.” *Van*, 61 F.4th at 1067 n.11. Here, Plaintiff must sort through *thousands* of class members to separate the 98.5% that Comanor claims were injured from the remainder.

Second, Plaintiff half-heartedly suggests that it can use Comanor’s probability estimates “to winnow uninjured class members.” Resp. 62. Not so. Comanor estimated the *percentage* of injured class members, but that estimate tells us nothing about “which specific TPPs managed to avoid paying for any fraudulently induced prescriptions,” *i.e.*, which TPPs are among Comanor’s 98.5% and which are among his 1.5%. 1-ER-22. Plaintiff thus concedes—fatally—that “individual inquiry is necessary to determine whether a TPP was injured.” Resp. 60; *see also* Dkt. 258, Pltfs. Class Cert. Reply at 11 (“[I]t is true it will take individual inquiry to determine if an individual TPP was injured.”).

Asacol is directly on point, yet Plaintiff ignores it. There, the plaintiff's expert estimated that 90% of class members would not have purchased a prescription drug in the but-for world, but he had no mechanism for separating the 90% from the other 10%. *See In re Asacol Antitrust Litig.*, 907 F.3d 42, 54, 57-58 (1st Cir. 2018). Likewise here, Comanor estimates that 98.5% of class members would have purchased less Actos in the but-for world, but even crediting that error-ridden estimate, Comanor has no mechanism for separating the 98.5% from the other 1.5%. As in *Asacol*, there is no way to find the proverbial needles in the haystack without reviewing 100% of the hay, and those individual inquiries themselves defeat predominance. *See id.* at 57-58; *id.* at 61 (Barron, J., concurring) (“[O]ne does not ordinarily set out to find a needle in a haystack by examining only ten percent of the straw”).

Neither Plaintiff nor the district court ever confronted Comanor's inability to distinguish uninjured TPPs from allegedly injured ones. Class certification should be reversed because Plaintiff has no “winnowing mechanism” that is “truncated enough to ensure that the common issues predominate, yet robust enough to preserve the defendants' Seventh Amendment and due process rights to contest every element of liability and to present every colorable defense.” *Rail Freight II*, 934 F.3d at 625.

IV. Plaintiff Cannot Overcome Superiority And Lilly-Specific Problems.

A. Class proceedings are not superior.

Plaintiff still has no plan for trying this case. Plaintiff's argument that it "showed how the *Neurontin* case was able to efficiently manage TPP claims nationally in a class context" concedes that Plaintiff has no endgame other than settlement. Resp. 73. Plaintiff cites a "proposed *settlement* notice program," 3-SER-378, which sheds no light on how this case could be *tried* given that "settlement-only class certification" eliminates the need to "inquire whether the case, if tried, would present intractable management problems," *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997). Indeed, *Neurontin* shows that a class-action trial would be impossible, as a *single* TPP that went to trial required a five-week trial with dozens of witnesses. Br. 58. Here, a trial of *thousands* of TPPs involving *thousands* of witnesses would be a "nightmare." 1-ER-15.¹⁰ No court has ever "allow[ed], under Rule 23, a trial in which thousands of class members testify." *Rail Freight II*, 934 F.3d at 627.

¹⁰ Plaintiff's assertion that Defendants "hinged their entire superiority challenge on predominance," Resp. 73, ignores that Defendants separately challenged superiority, pointing specifically to manageability problems illustrated by *Neurontin*, Dkt. 248, Takeda Opp'n to Class Cert. at 32.

B. Lilly-specific issues preclude certification.

Plaintiff's response to the Lilly-specific problems is to claim that Lilly conspired with Takeda "until July 2009," Resp. 74, but that is no answer. First, the class period runs through September 2010, so unless Plaintiff is abandoning all claims after July 2009, Plaintiff has conceded there is no class-wide method of establishing Lilly's liability for a portion of the class period during which 11 million Actos prescriptions were written. 4-ER-553. *Second*, even if Plaintiff could excise post-July 2009 claims, that would upend Comanor's 56% estimate, which depends on aggregated data *through 2010*. *Id.* These Lilly-specific issues underscore the broader predominance problems with this class.

CONCLUSION

The class-certification order should be reversed.

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